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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,899	09/29/2006	Hirofaka Kakita	2006_1644A	8311
513 7590 07/24/2008 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER MACAULEY, SHERIDAN R	
			ART UNIT 1651	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/594,899

Applicant(s)

KAKITA ET AL.

Examiner

SHERIDAN R. MACAULEY

Art Unit

1651

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

A response and amendment have been received and entered on March 10, 2008 and March 19, 2008. Claims 4 and 13 have been cancelled. Claims 1-3 and 5-12 are pending. Claims 5-9 are withdrawn due to a previous requirement for restriction. Claims 1-3 and 10-12 are examined on the merits in this office action.

Claim Objections

1. Objections to the claims have been withdrawn due to amendment.

Claim Rejections - 35 USC § 112

2. Rejections under 35 USC 112 have been withdrawn due to amendment.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-3 and 10-12 stand rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-3 recite an immaturable unialgal culture strain derived from spores of a marine macroalga of red algae, specifically the genus of *Gracilaria*, specifically *Gracilaria verrucosa*, *Gracilaria chorda*, or a subspecies of either of the two species, having characteristics that no matured female gametophytes are detectable and only matured tetrasporophytes are detectable,

said immaturable unialgal culture strain being obtained by the steps comprising: selectively collecting alga bodies, which have characteristics that no female gametophytes are detectable and only tetrasporophytes are detectable, from among matured bodies of marine macroalga of red algae growing in natural seawater area with intermixing of fresh water; washing the matured portions of the tetrasporophytes of the collected alga bodies with sterilized water or sterilized seawater; keeping the matured portions standing to cause release of spores; and culturing the released alga spores in sterilized seawater. Claims 10-12 recite an alga body obtained by growing the immaturable unialgal culture strain according to claim 1, specifically wherein wherein the red alga belong to the genus of *Gracilaria*, specifically *Gracilaria verrucosa*, *Gracilaria chorda*, or a subspecies of either of the two species.

5. There are populations of algae of the genus *Gracilaria* that grow in brackish water along the Japanese coast, specifically in estuaries or inlets, of which there are very few mature algae (as taught by Ryuta et al., Koseisha Koseikaku, 2001:27, 30, 31, 33, 48, 101-104; document cited in IDS; see p. 5 of English translation of International Preliminary Report on Patentability (previously cited) for description of the relevance of the document). *Gracilaria chorda* are known to inhabit the estuaries of the Japanese coast (as taught by Hirotaka et al., Bulletin of the Society of Sea Water Science, Japan, 2000, 54:310-315; document cited in IDS; see pp. 4-5 of English translation of International Report on Patentability (previously cited) for a description of the relevance of the document). Absent any evidence to the contrary, some of these strains would be expected to have the claimed characteristics as matured bodies. Since the algal culture

is not recited as being isolated or somehow removed from a natural environment, the claimed invention reads as a product of nature.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-3 and 10-12 stand rejected under 35 U.S.C. 102(b) as anticipated by Hirota et al. (Bulletin of the Society of Sea Water Science, Japan, 2000, 54:310-315; document previously cited; see pp. 4-5 of English translation of International Report on Patentability (previously cited) for a description of the relevance of the document) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hirota (2000) in view of Hirota (Heisei 10-12, Nendo Kagaku Gijutsu Sogo Kenkyu Itakuhi, Chiiki Sendo Kenkyu, Kenkyu Seika Holokusho, Zaidan Hojin Kochiken Sangyo Shinko Center, 2001, 176-192; document previously cited; see p. 5 of English translation of International Preliminary Report on Patentability (previously cited) for description of the relevance of the document). Claims 1-3 recite an immaturable unialgal culture strain derived from spores of a marine macroalga of red algae, specifically the genus of *Gracilaria*, specifically *Gracilaria verrucosa*, *Gracilaria chorda*, or a subspecies of either of the two species, having characteristics that no matured female gametophytes are detectable and only matured tetrasporophytes are detectable, said immaturable unialgal culture strain being obtained by the steps comprising: selectively collecting alga bodies, which have characteristics that no female gametophytes are detectable and only tetrasporophytes are detectable, from among matured bodies of marine macroalga of

red algae growing in natural seawater area with intermixing of fresh water; washing the matured portions of the tetrasporophytes of the collected alga bodies with sterilized water or sterilized seawater; keeping the matured portions standing to cause release of spores; and culturing the released alga spores in sterilized seawater. Claims 10-12 recite an alga body obtained by growing the immaturable unialgal culture strain according to claim 1, specifically wherein wherein the red alga belong to the genus of *Gracilaria*, specifically *Gracilaria verrucosa*, *Gracilaria chorda*, or a subspecies of either of the two species.

11. Hirotaka (2000) teaches the establishment of a unialgal culture strain of red alga of the species *Gracilaria chorda* by acquiring sporophytes from the *Gracilaria chorda* from an estuary in Japan and cultivating the spores that have been released from the sporophytes (see English abstract on p. 315 of the article and English translation of International Preliminary Report on Patentability, pp. 4-5). Since the culture strain described by Hirotaka (2000) appears to have been isolated from the same source and using similar techniques as the claimed culture strain, it would inherently possess the claimed characteristics. Therefore, Hirotaka (2000) anticipates all of the limitations of the cited claims.

12. In the alternative, if it is found that the culture strain of Hirotaka (2000) does not possess some of the claimed characteristics, the claimed cultured strain is rendered obvious by Hirotaka (2000) in view of Hirotaka (2001). Hirotaka (2001) teaches the cultivation of a unialgal culture strain from the genus *Gracilaria* from the same source as Hirotaka (2000), and teaches a technique for cultivation of the spores and continuous

cultivation of the strain as a stock unialgal culture (see English translation of the International Preliminary Report on Patentability, p. 5). One of ordinary skill in the art would have been motivated to use the cultivation techniques taught by Hirota (2001) to cultivate the strain of *Gracilaria chorda* taught by Hirota (2000) because a method of continuous cultivation for alga of the genus *Gracilaria* was known in the art, as taught by Hirota (2001), as was the cultivation of the species *Gracilaria chorda*, as taught by Hirota (2000). One could have substituted *Gracilaria chorda* in the method for the cultivation of *Gracilaria* spp. with a reasonable expectation of success because method of Hirota (2001) was known to be compatible with *Gracilaria* spp. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

13. The claims recite a composition and method in terms of a function, property or characteristic. For these claims, a 35 U.S.C. 102/103 rejection is proper when the composition of the prior art is the same as that of the claim but the property is not explicitly disclosed by the reference. Once rationale is provided to show that the claimed invention appears to be the same or similar to that of the prior art, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See MPEP § 2112.

14. Thus, the claims are anticipated by Hirota, or in the alternative, the claims are rendered obvious over Hirota (2000) in view of Hirota (2001).

Response to Arguments

15. Applicant's arguments filed March 10, 2008 and March 19, 2008 have been fully considered but they are not persuasive. Applicant argues that the amended claims are directed to statutory subject matter because they have been amended so that they no longer read on a product of nature. Applicant argues that the cited references fail to teach the claimed invention because the references do not teach a strain that was isolated by the process described in applicant's instant disclosure and that the strains of the cited references would not be suitable for long term storage.

16. In response to applicant's argument that the amended claims are directed to statutory subject matter, it is noted that the claims read on a product of nature for the reasons set forth above. Briefly, there are populations of algae of the genus *Gracilaria* that grow in brackish water along the Japanese coast, specifically in estuaries or inlets, of which there are very few mature algae. *Gracilaria chorda* are known to inhabit the estuaries of the Japanese coast and some of these strains would be expected to have the claimed characteristics as matured bodies. Since the algal culture is not recited as being isolated or somehow removed from a natural environment, the claimed invention reads as a product of nature. It is further noted that the instant claims are drawn to a product that is defined in terms of the process by which it is produced. Proper rationale has been provided to show that the claimed product appears to be the same or similar to that of the product of nature, regardless of the process by which it was produced. Applicant is advised that the claims may be amended to recite a product which is isolated or in some way removed from a natural setting, such as the recitation of "an

isolated immuturable unialgal culture strain.” Since the strain is not recited as isolated or in some way removed from a natural setting, applicant’s argument has not been found to be persuasive.

17. In response to applicant’s argument that the cited references fail to teach the claimed invention because the references do not teach a strain that was isolated by the process described in applicant’s instant disclosure and that the strains of the cited references would not be suitable for long term storage, it is noted that applicant has not provided evidence to show that the strains of the cited references would not be suitable for long term storage. Hirotaka (2001) describes the continuous cultivation of *Gracilaria* as a stock unialgal culture strain rather than the short term storage effect that applicant asserts would be inherent to the teachings of the reference. Furthermore, the instant claims are not directed to an isolated strain, and thus applicant’s argument that the strains of the reference were not isolated by the selective separation of alga bodies described in the instant disclosure strain is not relevant to the instant claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus, the cited references are still found to anticipate, or in the alternative render obvious, the claimed invention.

18. Therefore, applicant’s arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **SHERIDAN R. MACAULEY** whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

SRM